



## UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

D8/328,165 10/24/94 MASTERSON    SEAMINER   AZPURU, C					gon, D.C. 2023	<u> </u>
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MARILA J CHURCH BLAN. PHARMACRUTICAL RESEARCH CORP 3300 GOULD DR GAINESVILLE GA 30504  1502 DATE MAILED:  O1/20/95  This application has been examiner in charge of your application.  OMMISSIONER OF PATENTS AND TRADEMARKS  This application has been examined	08/328,165	10/24/94	MASTERSON			93.1806C.US
MARILA J CHURCH RLAN. PHARMACRUTICAL RESEARCH CORP 1300 GOULD DR GAINESVILLE GA 30504  1502 DATE MAILED:  O1/20/95  This is a communication from the examiner in charge of your application.  OMMISSIONER OF PATENTS AND TRADEMARKS  This application has been examined						EXAMINER
MARLA J CHURCH  1300 GOULD DR  GAINESVILLE GA 30504  1502  DATE MAILED:  O1/20/95  his is a communication from the examiner in charge of your application.  OMMISSIONER OF PATENTS AND TRADEMARKS  This application has been examined			15M1 (040)		AZPURU, C	,
SAINESVILLE GA 30504   1502   DATE MAILED:   O1/20/95	MARLA J CHUR	RCH	1341/0120	,	ART UNIT	PAPER NUMBER
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In is a communication from the examiner in charge of your application.    Chains application has been examined   Responsive to communication filled on   This action is made shortened statutory period for response to this action is set to expire   month(e), days from the date of this letter.    Chains   Motice of References Cited by Examiner, PTO-892.   Motice of Draftsman's Patent Drawing Review, PTO-1479.   Notice of Draftsman's Patent Drawing Review, PTO-1479.   Notice of Informal Patent Application, PTO-152.   Notice of Draftsman's Patent Drawing Review, PTO-1479.   Notice of Draftsman's Patent Drawing Review, PTO-152.   Notice of Draftsman's Patent Drawing Review, PTO-153.   Notice of Draftsman's Patent Drawing Review, PTO-153.   Notice of Draftsman's Patent Drawing Review, PTO-154.   Notice of Draftsman's Patent Drawing Review, PTO-154.   Notice of Draftsman's Patent Drawing Review PTO-155.   Information on How to Effect Drawing Changes, PTO-1474.   Notice of Draftsman's Patent Drawing Review PTO-155.   Information Dra	:AINESVILLE	GA 30504			1502	,
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Claims	OMMISSIONER OF PA	ATENTS AND TRADE	MARKS			
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are pending in the application on How to Effect Drawing Changes, PTO-1474.    Notice of References Cited by Examiner, PTO-892.   Notice of Art Cited by Applicant, PTO-1449.   Notice of Information on How to Effect Drawing Changes, PTO-1474.   Notice of Information on How to Effect Drawing Changes, PTO-1474.   Notice of Information on How to Effect Drawing Changes, PTO-1474.   Notice of Information on How to Effect Drawing Changes, PTO-1474.   Notice of Information on How to Effect Drawing Changes, PTO-1474.   Notice of Information on How to Effect Drawing Changes, PTO-1474.   Notice of Information Patent Application, PTO-152.   Notice of Information on How to Effect Drawing Changes, PTO-1474.   Notice of Information Patent Application, PTO-152.   Notice of Informa	(s					
Int I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:  1. Notice of References Cited by Examiner, PTO-892. 3. Notice of Informal Patent Drawing Review, PTO-152. 5. Information on How to Effect Drawing Changes, PTO-1474. 6. Notice of Informal Patent Application, PTO-152. 6. Notice of Informal Patent Application, PTO-152. 7. Notice of Informal Patent Application, PTO-152. 8. Notice of Informal Patent Application, PTO-152. 8. Notice of Informal Patent Application, PTO-152. 8. Notice of Informal Patent Application, PTO-152. 9. Notice of Informal Patent Applica				month(s), _	days	rom the date of this letter.
1. Notice of References Cited by Examiner, PTO-892. 3. Notice of Art Cited by Applicant, PTO-1449. 5. Information on How to Effect Drawing Changes, PTO-1474. 6. Notice of Informal Patent Application, PTO-152. 5. Olaims					ea. 35 U.S.C. 133	
Notice of Art Cited by Applicant, PTO-1449.  Information on How to Effect Drawing Changes, PTO-1474.  SumMARY OF ACTION  Claims	ert I. THE FOLLOWIN	(G ATTACHMENT(S)	ARE PART OF THIS ACT	ION:		
Notice of Art Cited by Applicant, PTO-1449.  Information on How to Effect Drawing Changes, PTO-1474.  SumMARY OF ACTION  Claims	1     Notice of Bate	propose Cited by Even	nings DTO 900	о ПР	4 D4	
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are pending in the application.  Claims					20 OF INTO THE P ELGI	it Application, F10-152.
are pending in the application. Solutions are withdrawn from consider and consider are withdrawn from consider are accepted.  Claims						
Claims	art II SUMMARY OF	ACTION				
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Claims						
Claims	Of the abo	ive, claims			a	re withdrawn from consider
are allowed.    Claims	L. Claims	-37				have been cancelled.
are rejected.  Claims	. 🗋	1				
are objected to.    Claims						
are objected to.    Claims	4. 🔀 Claims	8- YS				are rejected.
are subject to restriction or election requirement.  Claims						
This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.    This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.    The corrected or substitute drawings have been received on	5. LLI Claims				<del></del> -	are objected to.
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Formal drawings are required in response to this Office action.	This confication i					
The corrected or substitute drawings have been received on	ma application	HAS DOG!! HIGG WILL! HIR	ormai drawings brider 37 C	.F.M. 1.85 WINCH EIG	ассертавне тог ехан	mination purposes.
are acceptable; not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).  1. The proposed additional or substitute sheet(s) of drawings, filed on	3. Formal drawings	are required in respon	nse to this Office action.			
are acceptable; not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).  1. The proposed additional or substitute sheet(s) of drawings, filed on	. The corrected or	substitute drawings h	ave been received on		Under 37	C.E.B. 1.84 these drawings
examiner; disapproved by the examiner (see explanation).  The proposed drawing correction, filed	are acceptab	ie; 🗆 not acceptable (	see explanation or Notice	of Draftsman's Patent	Drawing Review,	PTO-948).
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Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certifled copy has been received one not been received to no						
3. Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.	I. L. The proposed dra	awing correction, filed		has been Dapprov	ed; 🗖 disapprove	d (see explanation).
Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.	. Acknowledgeme	nt is made of the claim	for priority under 35 U.S.	C. 119. The certified	copy has Kibeen	received  not been received
Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.	been filed in p	parent application, seri	al no. 07/786.4	oofiled on . ( /	019	
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## Part III DETAILED ACTION

Receipt is acknowledged of the preliminary amendment filed 10/24/95.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate description of the invention.

While the specification teaches improvement in nerve impulses, the claims appear to indicate a slowing of nerve conduction (See page 2, lines 5-24). Further, the specification appears to indicate that potassium ion flow is slowed, not nerve conduction. Clarification is requested.

- 1. Claims 38-45 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.
- 2. Claims 38-45 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The claims should refer to "said mono- or di-aminopyridine active agent" rather than "said active agent" in order to maintain proper antecedent basis. Correction is requested.

3. Claims 38-45 are rejected under 35 USC 112, sixth paragraph, as claiming a means or step for performing a specified function without the recital of structure, material, or acts in support thereof.

Specifically, applicant does not provide proper means/function by stating the effect of the release of the mono- or di-aminopyridine. It is suggested that the term "in need thereof" should be added after "patient".

## Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 38-41, and 45 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Davis et al, Bever et al., and Wesseling et al.

Both Davis et al. and Wesseling et al. disclose administration of 4-AP for improvement of neural conduction in MS (Davis et al.) and Alzheimer's (Wesseling et al). Further, Bever et al. teach that 3,4-DAP improves the response latencies in MS

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patients. Both Davis et al. and Bever et al. teach multiple oral dosing, which is inclusive of applicant's stipulation of an effective dosage level between 12-24 hours. The claims are clearly anticipated.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos Azpuru whose telephone number is (703) 308-0237.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (703) 308-2927. The fax phone number for this Art Unit is (703) 305-5408.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-2351.

PATENT EXAMINE